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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/737,245 | 12/15/2003 | Palani Bahu | 44368-0005-US.CON1 | 5841 |

25213 7590 02/21/2008
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| EXAMINER |
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KAM, CHIH MIN

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| ART UNIT | PAPER NUMBER |
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1656

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| MAIL DATE | DELIVERY MODE |
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02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/737,245

Applicant(s)

BALU, PALANI

Examiner

CHIH-MIN KAM

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-14, 16, 17 and 21-23 is/are allowed.
- 6) ☒ Claim(s) 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper-No(s)/Mail Date 1/17/08.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on January 17, 2008 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 10-14 and 16-23 are pending.

Applicants' amendment filed January 17, 2008 is acknowledged. Applicants' response has been fully considered. Claims 10 and 18 have been amended. Therefore, claims 10-14 and 16-23 are examined.

Withdrawn Claim Objections

3. The previous objection to claim 18 is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 4 in the amendment filed January 17, 2008.

Withdrawn Claim Rejections - 35 USC § 102

4. The previous rejection of claims 10-11, 18-20 and 23 under 35 U.S.C. 102(b) as being anticipated by Wrighton *et al.* (U. S. Patent 5,773,569), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 4-5 in the amendment filed January 17, 2008.

Withdrawn Claim Rejections -Obviousness Type Double Patenting

5. The previous rejection of claims 10-14 and 16-23, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent 6,703,480, is withdrawn in view of applicants' submission of a terminal disclaimer, and applicants' response at page 5 in the amendment filed January 17, 2008.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 18-20 are directed to a method of synthesizing a peptide dimer, comprising (a) providing first and second peptide chains linked to a linking moiety L_K , the chains each possessing multiple amino acid residues capable of disulfide bond formation upon oxidation; and (b) oxidizing in a single oxidation step said peptide chains in a manner effective to preferentially promote formation of disulfide bonds between residues in the same peptide chain relative to formation of disulfide bonds in different peptide chains, and wherein at least 50% of said peptide dimer comprises a peptide chain having an intrapeptide disulfide bond, wherein the first peptide chain is approximately 10 to 40 amino acid residues in length, binds to the erythropoietin receptor, and contains a sequence of amino acids $X_3X_4X_5GPX_6TX_7X_8X_9$, wherein X_3 is C or homocysteine (Hoc), X_4 is R, H, L or W, X_5 is M, F, I or nor-leucine (J), X_6 is selected from any one of the 20 conventional amino acids and J, X_7 is W, 1-naphthylalanine (B) or 2-naphthylalanine (U), X_8 is D, E, I, L, or V, and X_9 is C or Hoc; and the second peptide chain is approximately 10 to 40 amino acid residues in length, binds to the erythropoietin receptor, and contains a sequence of amino acids $X'_3X'_4X'_5X'_6X'_7X'_8X'_9$, wherein X'_3 is C or Hoc, X'_4 is R,

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H, L or W, X'5 is M, F, I or J, X'6 is selected from any one of the 20 conventional amino acids and J, X'7 is W, B or U, X'8 is D, E, I, L or V, and X'9 is C or Hoc.

The specification discloses the invention provides compounds in the form of peptide dimers that bind to and activate the EPO-R or behave as EPO agonists. The compounds have a first peptide chain R¹ and a second peptide chain R², wherein R¹ and R² may be the same or different, and are linked through a linking moiety, where R² is approximately 10 to 40 amino acid residues in length and contains a core sequence of amino acids X'3X'4X'5GPX'6TX'7X'8X'9 (page 4, line 27 through page 5, line 16), and provides many amino acid sequences as examples for R¹ and R² (See pages 13-15). However, the specification does not indicate the second peptide chain (R²) contains a sequence of amino acids X'3X'4X'5X'6X'7X'8X'9 without GP and T in the sequence. The lack of description of the second peptide chain (R²) containing a sequence of amino acids X'3X'4X'5X'6X'7X'8X'9 in the peptide dimer, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Conclusion

7. Claims 18-20 are rejected; and claims 10-14, 16-17 and 21-23 are free of art and appear allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

February 16, 2008